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(54) Multiple layer high strength balloon for dilatation catheter.

(57) A balloon for a dilatation catheter is formed to define relatively thin cone (C) and neck (N) segments at the opposite ends of the balloon (16) by forming the balloon in a plurality of separate very thin layers (18,20,22). The balloon is built up from a plurality of layers including an inner layer (22) which defines a complete balloon having a cylindrical mid-portion (22M), cones (22C) at its ends and necks (22N) at the ends of the cones. Each successive outer layer is trimmed to be shorter than the next adjacent innermost layer, the trimming being effected in the region of the cones. The composite balloon thus formed has a staggered wall thickness in the region of the cones as to define a cone that is approximately uniform in wall thickness in a direction extending toward the neck region. The resulting balloon will be better adapted to collapse to a low profile about the catheter shaft on which it is mounted.

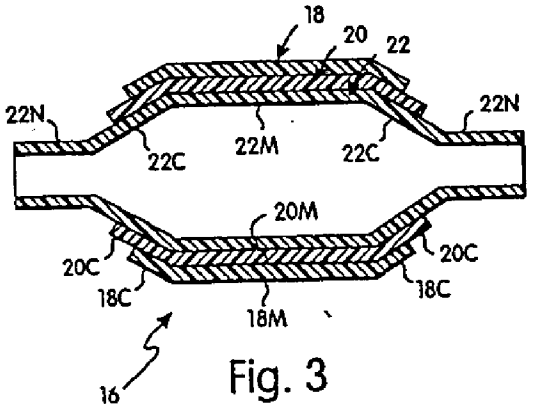

Fig. 3

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FIELD OF THE INVENTION

This invention relates to balloons used in dilatation catheters and to methods for making such balloons.

BACKGROUND OF THE INVENTION

Balloon dilatation catheters are used in the treatment of a variety of vascular conditions. Among the more frequent uses for balloon dilatation catheters is in vascular angioplasty of the peripheral and coronary arteries, by which arteries obstructed by plaque (formed by fatty deposits such as cholesterol) are dilated to improve blood flow through the artery. In a typical angioplasty procedure, a balloon dilatation catheter is inserted percutaneously into the patient's arterial system and then is advanced and steered through the patient's arteries until the distal end of the catheter, that carries the balloon, is disposed adjacent the obstruction (stenosis). The balloon end of the catheter then is advanced into the stenosis and, when so placed, is inflated under high pressure, to dilate the artery in the region of stenosis. The catheter typically is used with a small diameter steerable guidewire which is used to guide the catheter to the stenosis. By way of example, such a catheter and guidewire system is disclosed in U.S. Patent 4,545,390 issued October 8, 1985 (Leary), reference thereto being made for a more complete description of the catheter and guidewire system and its manner of use.

It is desirable, particularly in coronary angioplasty in which the coronary arteries are narrow and tortuous, and in which the stenoses often may be calcified and difficult to dilate, that the catheter and its balloon meet a number of stringent requirements. Among these are that the balloon be capable of folding down to a low profile about the catheter shaft so that the balloon portion of the catheter is more readily insertable through the stenosis. Inability to insert the balloon portion of the catheter into the stenosis is among the more frequent causes of an unsuccessful angioplasty. Also among the important characteristics of the balloon dilatation catheter is that it should be "trackable", that is, it must be able to follow and advance over the guidewire and through the artery even when the artery is highly tortuous with many sharp bends. An additional important characteristic of the balloon is that it should have a high burst strength so that it may dilate hard, calcified stenoses as well as those that require less force for the dilation.

In order to improve the low profile and trackability characteristics of the character in the region of the balloon, efforts have been made to develop dilatation balloons having very thin walls so that the balloon will fold more readily to a low profile about the catheter shaft and also so that the balloon will be more flexible, thus enhancing the ability of the catheter to bend in the region of the balloon, thereby achieving improved trackability. To that end, significant advances have been made in the art. U.S. Patent 4,490,421 describes the manufacture of dilatation balloons by which balloons may be made having a high burst strength and significantly thinner walls than its predecessors. The procedure was improved further, as described in U.S. Patent Application Serial No. 001,759, filed January 9, 1987 to enable the manufacture of high strength balloons having even thinner, more flexible walls.

Although the foregoing advances in manufacturing thinner walled balloons have significantly improved the catheters, those efforts have been directed at the cylindrical midportion of the balloon. The cones and necks of the balloon, at the ends of the cylindrical midportion, are not as thin as the cylindrical midportion. Each cone is of increasing wall thickness in a direction away from the cylindrical midportion of the balloon and reaches a maximum wall thickness at its juncture with the necks. The wall thickness of the neck is at that maximum value throughout their length. The increased wall thickness of the balloon in the regions of the cones and the necks detracts from the ability of the balloon to collapse to a low profile as well as the ability of the balloon to track along the guidewire along sharp tortuous paths. It would be desirable, therefore, to provide a balloon for a dilatation catheter in which the wall thickness in the cone and neck portions is reduced and, preferably, is not substantially greater than the thickness in the cylindrical midportion of the balloon. It is among the objects of the invention to provide such a balloon and method for its manufacture.

SUMMARY OF THE INVENTION

The balloon of the present invention is formed from a plurality of thin layers rather than from a single unitary layer, the aggregate wall thickness of the layers being approximately equal to the wall thickness of a conventional single layer balloon in the cylindrical midportion. The balloons are made by blow molding a first balloon in a cylindrical mold from a thin walled polymeric tubular parison, as described in U.S. Patent Application Serial No. 001,759, filed January 9, 1987. The balloon then is removed from the mold and is trimmed at its ends to remove the necks and a portion of the cones. The trimmed balloon then is replaced in the mold against the mold walls. A second polymeric tube then is inserted into the mold and it is blow molded, expanding outwardly against the confines of the cylindrical mold and the inner surface of the

first trimmed balloon. Then the combined first and second balloons are removed from the mold and the second balloon is trimmed at its ends to be slightly longer than the first trimmed balloon. The combined first and second balloons then are replaced in the mold and the process is repeated, inserting a tubular polymeric parison in the mold and blow molding it to expand into engagement with the second trimmed balloon. The combined first, second and third balloons then are removed from the mold, the ends of the third tube may be trimmed to leave the necks on the third, innermost balloon. The resulting balloon thus has cones in which the wall thickness does not increase substantially and in which the wall thickness in the neck region also is substantially less than with prior techniques for making such balloons. The resulting balloon is more flexible in the cone and neck region than with prior balloons.

It is among the objects of the invention to provide a balloon for a dilatation catheter and a method for making the balloon.

Another object of the invention is to provide a balloon dilatation catheter having improved low profile and trackable characteristics in the region of its cones and necks.

Another object of the invention is to provide a dilatation balloon construction in which the cone and neck regions are not substantially greater in wall thickness than the cylindrical midportion of the balloon.

A further object of the invention is to provide a balloon for a dilatation catheter in which the balloon is formed from a plurality of thin layers in intimate contact with each other.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is an illustration of a balloon dilatation catheter;

FIG. 2 is an enlarged diagrammatic cross-sectional illustration of a conventional balloon in which the thicknesses of the balloon material are highly exaggerated to illustrate the relative thicknesses of the balloon at the central cylindrical portion, the cone portion and the neck portion; and

FIG. 3 is an enlarged diagrammatic cross-sectional illustration of a balloon made in accordance with the present invention;

FIG. 4 is an illustration of the mold process used in making the balloon; and

FIGS. 5A-5E are diagrammatic illustrations of the mold and the sequence of steps for making the balloon of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates a balloon dilatation catheter of the type with which the present invention is concerned. The catheter 10 has a proximal end (to the left in FIG. 1) and a distal end (to the right in FIG. 1). An elongate flexible shaft 12 typically is provided with appropriate lumens, for example, a guidewire lumen (not shown) that extends the length of the shaft and an inflation lumen (not shown) that extends from the proximal end of the shaft to the distal region of the shaft and communicates with the interior of a dilatation balloon 14 that is mounted to the distal region of the shaft. Reference is made to the aforementioned Leary Patent 4,545,390 for further description of the type of catheter, the Leary patent being incorporated by reference herein. By way of example, the catheter shaft 12 may be of the order of 150 cm long and of the order of 0.50" diameter. The balloon may vary in size from about 1.5 mm to 4.5 mm diameter, for coronary use. The balloon may be considered as having a constant diameter cylindrical midportion 14M which expands to the nominal diameter, a pair of end cones 14C at the ends of the midsection 14M and a pair of neck sections 14N that extend outwardly from the narrow ends of the cones 14C. The balloon 14 is attached to the catheter shaft 12 by adhesively bonding the necks 14N to the catheter shaft 12.

FIG. 2 shows a conventional balloon formed in one-piece, shown with its wall thicknesses exaggerated for ease of illustration. Such a balloon may be made according to the procedure described in U.S. Patent 4,490,421 and U.S. Application Serial No. 001,759, filed January 9, 1987, the disclosures of which are hereby incorporated by reference. The balloon is formed in a biaxially stretching process that includes blow molding in a mold of the type illustrated in FIG. 4. As described in further detail in the Levy patent, which is incorporated herein by reference, a tubular parison 15 of uniform inner and outer diameters and wall thickness is extended through the mold 17. The tubular parison is stretched axially and is blow molded radially within the mold 17. The portion of the tube 15 that forms the cylindrical midportion 14M is subjected to a greater degree of radial stretching than the neck portions 14N. Consequently, the midportion 14M will have less wall thickness than the neck portion 14N. The cones 14C are radially stretched to progressively varying degree as the diameter of the cones change. Thus, as illustrated in FIG. 2 the midportion 14M will have the thinnest wall, the

neck 14N will have the thickest wall and the cones 14C will have a progressively increasing wall thickness in a direction extending from the ends of the midportion 14M to the necks 14N. The cones 14C and necks 14N thus are thicker than required. The increased thickness in the cones adversely affects the ability of the balloon to contract to a low profile. The greater thickness of the cones and the necks detracts from the trackability of the catheter.

In accordance with the present invention, the balloon is formed from a plurality of relatively thin layers rather than a single unitary relatively thick layer. The configuration of a balloon made in accordance with the invention is shown in FIG. 3 in highly diagrammatic enlarged and exaggerated form. The illustrated balloon, indicated generally at 16, is formed from three layers including an outer layer 18, an intermediate layer 20 and an inner layer 22. The layers 18, 20, 22 are each in continuous intimate contact with each other and need not be adhesively attached. The balloon 16 is formed in a procedure illustrated diagrammatically in FIGS. 5A-5. The mold 17, described in further detail in the Levy patent, receives a tubular parison 15 of the polymer from which the balloon is to be formed. The parison is relatively thin walled. The parison is stretched and expanded biaxially by combined axial stretching and blow molding as described in the Levy patent, to form a balloon having cones and neck extensions. In accordance with the invention, a first such balloon 18 is formed and is heat set at an elevated temperature as described in said Application Serial No. 001,759 and is then removed from the mold. The first balloon then is trimmed at each end between the ends of its cones as suggested at 24 in FIG. 5A, thus leaving a balloon midportion 18M and a pair of partial cones 18C. The first balloon, thus trimmed, then is replaced in the mold. A second elongate tubular parison 20P then is inserted into the mold as suggested in FIG. 5B and it is biaxially stretched and expanded. When the second parison 20P expands, it contacts fully and intimately the inner surface of the outer layer 18 contained within the mold. The second balloon thus formed also is heat set. After the intermediate balloon 20 has been formed, the combined outer and intermediate balloons 18, 20 are removed from the mold. The ends of the intermediate balloon layer 20 then are trimmed as suggested at 26 in FIG. 5C so that the intermediate cones 20C extend slightly outwardly of the shorter outer cones 18C. The two layer, partially formed balloon then may be reinserted into the mold and the process repeated with a third parison 22P of polymeric material as suggested in FIG. 5D. When the third layer 22 has been formed, the assembly of layers is again removed from the mold. The ends of the inner layer 22 then may be trimmed as suggested at 28 in FIG. 5E to leave the necks 22N and an exposed portion of the cones 22C. The balloon thus formed may be attached to the catheter shaft 12 by adhesively bonding the necks 22N to the catheter shaft.

It will be appreciated from the foregoing that the neck of the multiluminal balloon which is formed from an initial thin parison, although not expanded as much as the balloon midportion still is substantially thinner than the corresponding neck in a balloon formed in one-piece in a single layer. The regions of the cones similarly define a series of stepped thicknesses in which the thickness of the cone decreases in a direction extending away from the balloon midportion. Thus, although the cone segment in each of the three layers will tend to have increased thickness in an outward direction, the stepped down configuration of the cones, considered together, results overall in a cone thickness that is relatively small. For example, even in a thin wall high strength balloon made in accordance with the procedure described in Application Serial No. 001,759, the wall thickness in the cone ranges from about 0.0003" at its juncture with the cylindrical midportion to approximately 0.001" at its juncture with the neck. The neck portion may be of the order of 0.001".

By way of example, balloons made in accordance with the present invention may be formed from a tubular parison of polyethylene terephthalate having an inner diameter of the order of 0.0168" inner diameter and a wall thickness of the order of 0.0022". The parison is biaxially stretched about 3X in an axial direction and radially about 7X inner diameter stretch and about 5.5X outer diameter stretch. The resulting balloon will have a wall thickness in the cylindrical midportion region of the order of 0.0001", a cone thickness gradually increases from 0.0001" to about 0.0004" where the cone joins the neck and a neck portion having a wall thickness of the order of 0.0004". The aggregate wall thickness in the cylindrical midportion of the multiple layers is of the order of 0.0003" which is comparable to currently commercially available balloons.

From the foregoing, it will be appreciated that the invention provides a new construction for a dilatation balloon, a new method for its manufacture and a new resulting catheter that will display improved characteristics as to trackability and reduced profile. It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other embodiments, modifications and equivalents may be apparent to those skilled in the art without departing from its spirit.

Having thus described the invention, what I desire to claim and secure by Letters Patent is:

Claims

1. In a balloon for a dilatation catheter, the balloon being formed from polymeric material and having a cylindrical midportion, an outwardly tapering conical portion at each end of the midportion and a cylindrical neck portion at the ends of the conical portions, the improvement comprising the balloon being formed in at least two layers including an inner and outer layer, one of which is shortened and terminates in the region of the cones of the other.

2. A balloon as defined in claim 1 wherein there are at least three layers with at least one layer being disposed between the inside layer and the outside layer, the intermediate layer being of a length between that of the inside and outside layers.

3. A balloon as defined in claims 1 or 2 wherein the layers are in intimate adhesive-free contact with each other.

4. A balloon as defined in claims 1 or 2 wherein the more inwardly disposed layers are of greater length than the more outwardly disposed layers.

5. A balloon dilatation catheter comprising an elongate flexible shaft having a dilatation balloon mounted at the distal end, the balloon being formed from polymeric material and having a cylindrical midportion, an outwardly tapering conical portion at each end of the midportion and a cylindrical neck portion at the ends of the conical portions, the balloon being formed in at least two layers including an inner and outer layer, one of which is shortened and terminates in the region of the cones of the other, the necks of the balloon being adhesively attached to the shaft.

6. A balloon dilatation catheter as defined in claim 5 wherein there are at least three layers with at least one layer being disposed between the inside layer and the outside layer, the intermediate layer being of a length between that of the inside and outside layers.

7. A balloon dilatation catheter as defined in claims 5 or 6 wherein the layers are in intimate adhesive-free contact with each other.

8. A multi-layered balloon for a dilatation catheter, the balloon being formed from a plurality of layers of polymeric material and having a cylindrical midportion, cones extending from the ends of the midportion and necks extending from the ends of the cones, the cylindrical midportion having a predetermined thickness, the layers thickness of the cones and the neck portions being not substantially greater than the thickness of the midportion.

9. A balloon dilatation catheter having an elongate flexible shaft and a multi-layered balloon formed from a plurality of layers of polymeric material, the balloon being mounted to the distal end of the shaft, the balloon having a cylindrical midportion, cones extending from the ends of the midportion and necks extending from the ends of the cones, the cylindrical midportion having a predetermined thickness, the thickness of the cones and neck portions being not substantially greater than the thickness of the midportion.

10. A method for making a dilatation balloon having a cylindrical midportion, cones extending from the ends of the midportions and necks extending from the ends of the cones, the balloon being formed from a polymeric material and comprising:

    blow molding a first balloon in a mold;

    removing the first balloon from the mold and trimming its ends in the region of the cones;

    placing the trimmed first balloon in the mold and then blow molding a subsequent balloon into intimate contact with the next previously placed balloon segment;

    removing the assembly of balloon layers from the mold and trimming the last formed layer to define the neck portion of the balloon.

11. A method for making a dilatation balloon as defined in claim 10 wherein the balloons are stretched axially during their formation whereby the balloon layers are biaxially oriented.

12. A method for making a dilatation balloon as defined in claims 10 or 11 further comprising heat setting each balloon layer after its formation at a temperature elevated above the temperature at which the balloon layers are blow molded.

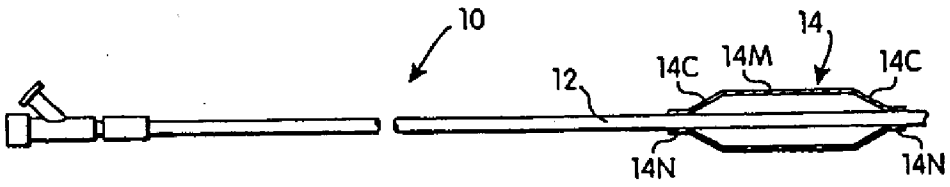

Fig. 1

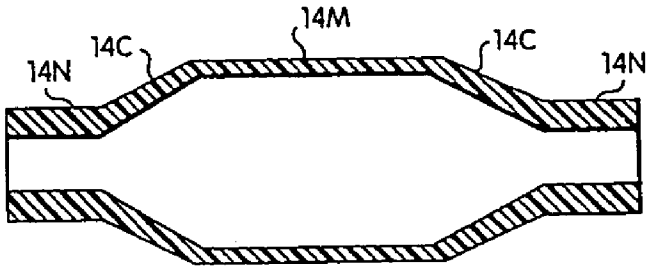

Fig. 2

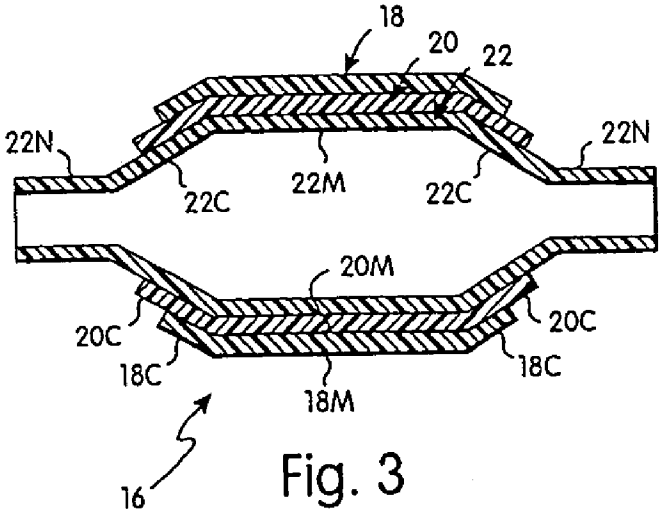

Fig. 3

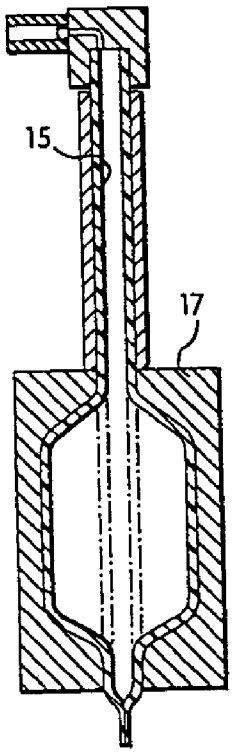

Fig. 4

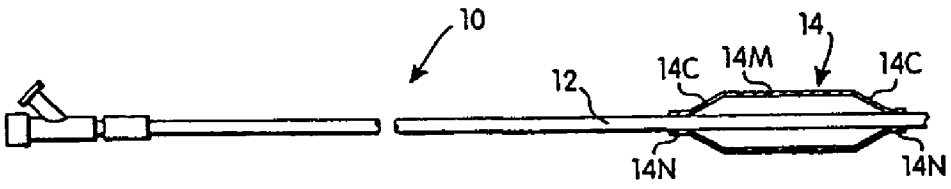

Fig. 1

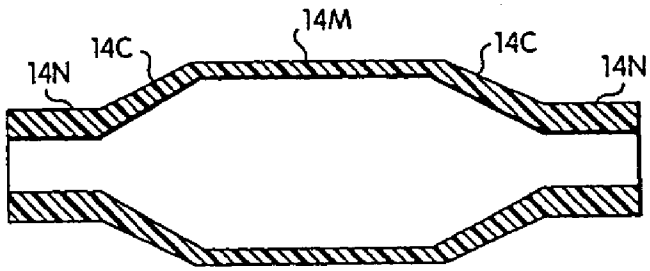

Fig. 2

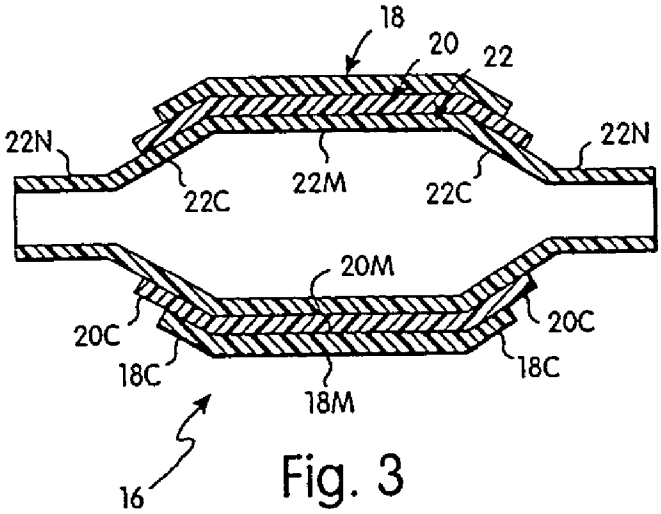

Fig. 3

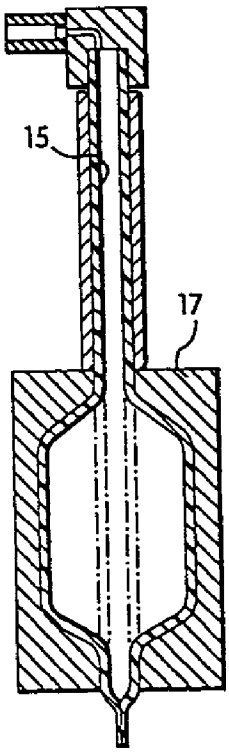

Fig. 4

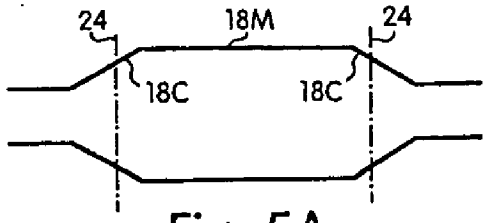

Fig. 5A

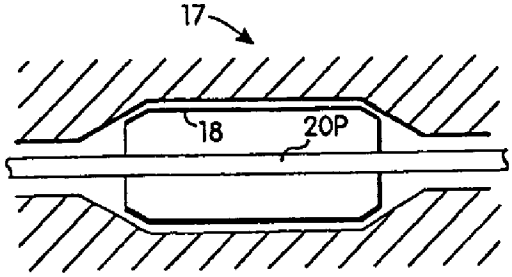

Fig. 5B

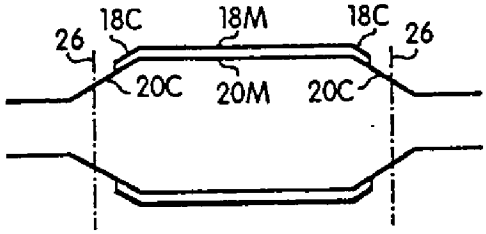

Fig. 5C

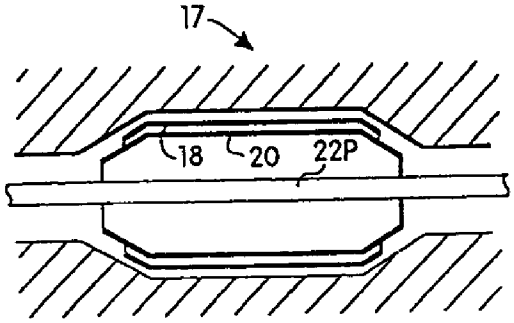

Fig. 5D

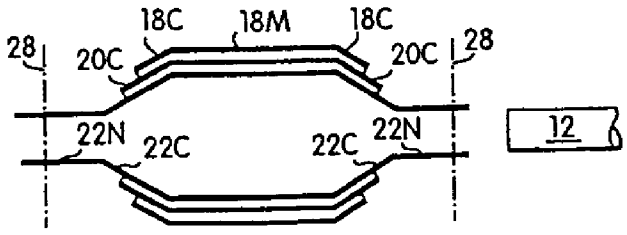

Fig. 5E

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 91 30 3901

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 357 562 (MEADOX MEDICALS, INC.) * page 4, line 29 - page 5, line 46; figures 2,5,9,10 *	1,3,5,7-9	A 61 M 25/00
X	FR-A-2 328 482 (SHERWOOD MEDICAL INDUSTRIES INC,) * page 5, line 23 - page 9, line 25; figures *	1,3,5,7-9	
A	US-A-4 327 736 (INOUE) * abstract; figure 1 *	1-9	
A	US-A-3 539 674 (DERENIUK ET AL.) * column 4, line 27 - line 64; figure 6 *	1-9	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	23 July 91	MIR Y GUILLEN V.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
Y: particularly relevant if combined with another document of the same catagory
A: technological background
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T: theory or principle underlying the invention

E: earlier patent document, but published on, or after the filing date
D: document cited in the application
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&: member of the same patent family, corresponding document